

Opportunities for Adherence Research in Clinical Trials: Lessons Learned in Women's Health Studies

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Adherence Research Challenges in Clinical Trials

Ancillary Nature of Adherence Research in Clinical Trials

- Lack of input from behavioral scientists at study planning stage
- Inadequate funding to seriously address adherence issues within the trial
- Missed opportunity for relatively cost-effective method to study adherence (as opposed to de novo studies)

Conflict Between Recruitment Process and Adherence Needs of Trials

- “Marketing” techniques in recruitment
 - selling the study to potential participants
 - screening out potential non-adherent participants
- Pressures to reach recruitment goals with limited budgets

Inadequate Tracking of Screening, Adherence and Critically Related Factors

- Participants not fully profiled with relevant data entered during screening and thereafter
- Inadequate assessment of factors key to profiling adherence patterns

Desperation Adherence- "Enhancement" Interventions

- Multiple adherence interventions
- “Interventions” not tracked w/r to success or cost-effectiveness
- Probable “Hawthorne” effect ignored; costly interventions may simply reflect additional time/attention to both staff and participants

Defining and Measuring Adherence

- Methods for adherence ascertainment highly varied within and among trials and not theory driven
- The relative reliability and validity of various adherence measures a neglected issue

Inadequate Modeling and Analyses of Adherence

- Over-reliance on “old” models/theories with limited innovative work evolving
- Theories not driving variables collected w/in clinical trials
- Data analytic techniques used in clinical trials inappropriate for complex modeling needed for adherence research

Dissemination of Information Gained Regarding Adherence is Inadequate

- Limited time, resources, or efforts directed toward dissemination resulting in lots of “Recreating the Wheel”
- Lack of outlets and funding support for this type of research

Given all the Problems, Why Conduct Adherence Research within Clinical Trials?

- Extensive data on clinical status and demographics of study population
- Large, diverse study populations allow for complex adherence data modeling
- Longer timeframe of clinical trials permit modeling of change in adherence patterns over time

Why Conduct Adherence Research within Clinical Trials?, cont. . .

- Potential to strengthen the power and relevance of the clinical study
- “Learnings” relevant to dissemination of findings from the clinical study

Learnings From Women's Health Research

- Aggressive study monitoring and modeling of data to understand differences among sites in adherence/retention
- Development of tracking techniques to assist individual sites in assessing adherence current and potential problems

Learnings From Women's Health Research, cont. . .

- Development and support of multi-disciplinary writing teams to develop and test theoretical models of adherence
- Support for specialists in structural equation modeling and psychometrics to analyze data
- Support for dissemination of findings

Where Do We Go From Here?

- Mine extant clinical trial datasets--
Provide resources to take advantage of existing data sets w/r to:
 - innovative and complex theoretical modeling; and
 - innovative data analytic techniques

Where Do We Go From Here?, cont. . .

- Provide opportunities for dissemination of findings from extant and new data
 - through meetings, journal articles, etc.
 - through development of an adherence handbook for clinical trial investigators
- Include behavioral scientists with expertise in adherence **research** at clinical trial design phase

Where Do We Go From Here?, cont. . .

- Provide opportunities for folks “in the trenches” to discuss their experiences and knowledge on adherence
- Provide set-aside funds at trial onset to randomly test and assess strategies designed to enhance adherence within the ongoing trial

Summary and Conclusions

- Adherence is an ongoing challenge in both clinical research and practice
- Substantial data are available within existing data sets that should be mined & disseminated
- Adherence research within clinical trials represents an untapped opportunity to cost-effectively advance knowledge